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| Γ   | APPLICATION NO.       | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---|-----------------------|----------------|----------------------|-------------------------|------------------|--|
|   | 09/974,573            | 10/09/2001     | Roger Williams       | ONYX1048.ORD            | 8292             |  |
|   | 7:                    | 590 09/26/2003 | *                    |                         |                  |  |
|   | Gregory Giotta, Ph.D. |                |                      | EXAMI                   | EXAMINER         |  |
| Vice President and Chief Legal Counsel ONYX Pharmaceuticals, Inc. |                       |                |                      | SWOPE, SHERIDAN         |                  |  |
|   | 3031 Research         |                |                      | ART UNIT                | PAPER NUMBER     |  |
|   | Richmond, CA          | 94600          | 1652                 | 1652                    | / >              |  |
|   |                       |                |                      | DATE MAILED: 09/26/2003 | (()              |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No.         | Applicant(s)                                       |  |  |  |
|---|---|-------------------------|--|--|--|--|
|   |   | 09/974,573              | WILLIAMS ET AL.                                    |  |  |  |
|   | Office Action Summary   | Examiner                | Art Unit   |  |  |  |
|   |   | Sheridan L. Swope       | 1652   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                         |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                         |  |  |  |  |
| Status  | Deprending to communication(s) filed on   |                         |  |  |  |  |
| 1)[   | Responsive to communication(s) filed on   |                         |  |  |  |  |
| 2a)☐  | ,—  | s action is non-final.  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |   |                         |  |  |  |  |
| ·   | Claim(s) <u>1-36</u> is/are pending in the application  |                         |  |  |  |  |
| •   | 4a) Of the above claim(s) is/are withdraw   |                         |  |  |  |  |
|   | 5) Claim(s) is/are allowed.   |                         |  |  |  |  |
|   | 6) Claim(s) is/are rejected.  |                         |  |  |  |  |
|   | Claim(s) is/are objected to.  |                         |  |  |  |  |
| ·   | Claim(s) <u>1-36</u> are subject to restriction and/or e  | election requirement    |  |  |  |  |
| <u>-</u>  | on Papers   | section requirement.    |  |  |  |  |
|   | Γhe specification is objected to by the Examiner  | ·.                      |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |                         |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                         |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |   |                         |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                         |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |   |                         |  |  |  |  |
| Priority u  | nder 35 U.S.C. §§ 119 and 120   |                         |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                         |  |  |  |  |
|   | a) ☐ All b) ☐ Some * c) ☐ None of:  |                         |  |  |  |  |
| ·   | 1.☐ Certified copies of the priority documents  | s have been received.   |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No  |                         |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |                         |  |  |  |  |
|   | 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).                      |                         |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |   |                         |  |  |  |  |
| Attachment(s)   |   |                         |  |  |  |  |
| 1) Notice   | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal P | (PTO-413) Paper No(s) latent Application (PTO-152) |  |  |  |

U.S. Patent and Trademark Office PTOL-326 (Rev. 04-01)

Page 2

Application/Control Number: 09/974,573

Art Unit: 1652

### **DETAILED ACTION**

### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, drawn to a PI3Kγ crystal, classified in class 435, subclass 194.
- II. Claims 2 and 3, drawn to a method of modulating substrate binding by modifying the phospholipid domain, classified in class 435, subclass 440.
- III. Claims 4-7, 13, 14, 20, 21, 26, 27, 33, and 34, drawn to a polypeptide fragments and mutants of PI3Ky, classified in class 435, subclass 194.
- IV. Claims 8, 15, 22, 28, and 35, drawn to an antibody to the phospholipid binding domain, classified in class 530, subclass 388.26.
- V. Claims 9, 16, 23, 29, and 36, drawn to nucleic acid molecules classified in class 536, subclass 23.2.
- VI. Claims 10, in part, and 11, drawn to a method of modulating catalysis comprising modifying His968 of PI3Kγ by contacting an antibody specific for a region comprising, classified in class 435, subclass 194.
- VII. Claims 10, in part, and 12, drawn to drawn to a method of modulating catalysis comprising modifying His968 of PI3Kγ by mutating His968, classified in class 435, subclass 194.
- VIII. Claims 17, in part, and 18, drawn to a method of modifying RAS activity by modifying PI3Kγ by mutation, classified in class 435, subclass 199.
- IX. Claims 17, in part, and 19, drawn to a method of modifying RAS activity by modifying PI3Kγ by antibody contact, classified in class 435, subclass 199.

Application/Control Number: 09/974,573

Art Unit: 1652

X. Claim 24, drawn to a method of inhibiting the binding of PI3Ky to membranes by

Page 3

modifying amino acid residues, classified in class 435, subclass 194.

XI. Claim 25, drawn to a method of inhibiting the binding of PI3Ky to membranes

using antibody contact, classified in class 435, subclass 194.

XII. Claims 30-32, drawn to a method of modulating protein-protein interactions with

PI3Ky by modifying the B-helices, classified in class 435, subclass 194.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of

the following can be shown: (1) that the process as claimed can be used to make another and

materially different product, (2) that the product claimed can be used in a materially different

process of using that product, or (3) that the product claimed can be made by another and

materially different process (MPEP § 806.05(h)). These inventions are different or distinct for

the following reasons.

List of justifications:

This application contains claims directed to the following patentably distinct species of

the claimed invention: SPECIES: Invention III, IV, V, VIII

For Invention III:

A. A fragment of PI3Ky;

B. A mutein of PI3Ky comprising a mutation a Lys807;

C. A mutein of PI3Ky comprising a mutation a Lys808;

D. A mutein of PI3Ky comprising a mutation a Lys947;

Application/Control Number: 09/974,573 Page 4

Art Unit: 1652

E. A mutein of PI3Kγ comprising a mutation a Lys973.

## For Invention IV:

- F. An antibody to a fragment of PI3Kγ;
- G. An antibody to a mutein of PI3Ky comprising a mutation a Lys807;
- H. An antibody to a mutein of PI3Kγ comprising a mutation a Lys808;
- I. An antibody to a mutein of PI3Ky comprising a mutation a Lys947;
- J. An antibody to a mutein of PI3Ky comprising a mutation a Lys473.

### For Invention V:

- K. A nucleic acid encoding a fragment of PI3Kγ;
- L. A nucleic acid encoding a mutein of PI3Ky comprising a mutation a Lys807;
- M. A nucleic acid encoding a mutein of PI3Ky comprising a mutation a Lys808;
- N. A nucleic acid encoding a mutein of PI3Ky comprising a mutation a Lys947;
- O. A nucleic acid encoding a mutein of PI3Ky comprising a mutation a Lys473.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 2, 10, 17, 24, 30, and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

Application/Control Number: 09/974,573 Page 5

Art Unit: 1652

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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PRIMARY EXAMINER
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